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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR		ATTORNEY DOCKET NO.
09/488,2	02 01/19/	00 LATORRE	G	028870-057
021839		HM12/0824		EXAMINER
BURNS DOANE SWECKER & MATHIS L L P			BEN	NETT, R
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Please find below and/or attached an Office communication concerning this application or proceeding.

**Commissioner of Patents and Trademarks** 

08/24/00

	Application No.	Applicant(s)
•	09/488,202	LATORRE ET AL.
Office Action Summary	Examiner	Art Unit
	Rachel M. Bennett	1615
The MAILING DATE of this communication app Period for Reply		
A SHORTENED STATUTORY PERIOD FOR REPI THE MAILING DATE OF THIS COMMUNICATION		ONTH(S) FROM
<ul> <li>Extensions of time may be available under the provisions of 3 after SIX (6) MONTHS from the mailing date of this community.</li> <li>If the period for reply specified above is less than thirty (30) do be considered timely.</li> <li>If NO period for reply is specified above, the maximum statute communication.</li> <li>Failure to reply within the set or extended period for reply will, Status</li> </ul>	inication.  ays, a reply within the statutory min  bry period will apply and will expire	nimum of thirty (30) days will SIX (6) MONTHS from the mailing date of this
1) Responsive to communication(s) filed on 19	January 2000 .	
2a) This action is <b>FINAL</b> . 2b) ⊠ T	his action is non-final.	
3) Since this application is in condition for allow closed in accordance with the practice unde		
Disposition of Claims		
4) Claim(s) 1-16 is/are pending in the application	n.	
4a) Of the above claim(s) is/are withdr	awn from consideration.	
5) Claim(s) is/are allowed.		
6)⊠ Claim(s) <u>1-16</u> is/are rejected.		
7) Claim(s) is/are objected to.		
8) Claims are subject to restriction and/	or election requirement.	
Application Papers		
9) The specification is objected to by the Examin	ner.	
10) The drawing(s) filed on is/are objected	to by the Examiner.	
11) The proposed drawing correction filed on		disapproved.
12) The oath or declaration is objected to by the i		
Priority under 35 U.S.C. § 119		
13) Acknowledgment is made of a claim for foreig	ın priority under 35 U.S.C. δ	119(a)-(d).
a) ☐ All b) ☐ Some * c) ☐ None of the CERTI		, , , ,
1.☐ received.	TIED copies of the phonty of	oddinents have been.
2. ☐ received in Application No. (Series Co	de / Serial Number)	
3. ☐ received in this National Stage applicat		ıreau (PCT Rule 17 2(a))
* See the attached detailed Office action for a lis		
14) Acknowledgement is made of a claim for dom	·	
Attachment(s)	40\ 🗀	Summany /DTO 412\ Danas Ma/a\
<ul> <li> S    Notice of References Cited (PTO-892)</li> <li> G    Notice of Draftsperson's Patent Drawing Review (PTO-948)</li> <li> T    Information Disclosure Statement(s) (PTO-1449) Paper No(s)</li> </ul>	19) Notice of	Summary (PTO-413) Paper No(s) Informal Patent Application (PTO-152) ibstitute PTO-948 .

Art Unit: 1615

#### DETAILED ACTION

Receipt is acknowledged of applicants Preliminary Amendment received on January 19, 2000, Information Disclosure Statement received on May 25, 2000, and Petition for Extension of Time, Combined Declaration and Power of Attorney, and Statement Claiming Small Entity Status were received on June 16, 2000. Also, Supplemental Information Disclosure Statement was received on June 28, 2000.

### Specification

#### Claim Rejections - 35 USC § 112

- 1. The following is a quotation of the first paragraph of 35 U.S.C. 112:
  - The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
- 2. Claims 14 & 15 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In claim 14, the method of treating nails is excluded to mammals other than humans and more specifically in claim 15 to dogs or cats. However, in the specification, page 3 lines 16 and 17, it states "it would be advantageous to provide compositions and methods of treating nails in humans (as well as other mammals)". Also in the applicants' examples, the nails were that of a human with no examples of the composition being used on other mammals especially dogs and cats. Therefore, while claim 14 states "mammals other than

Art Unit: 1615

humans" and claim 15 states "the mammals are cats and dogs", the specification does not provide this written description of the method of treatment of the claimed invention.

- 3. The following is a quotation of the second paragraph of 35 U.S.C. 112:
  The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 4. Claims 8 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 8 and 12 are indefinite because applicant does not clearly define "and other cosmetically useful additives" in the claims. The applicant is counseled to cancel phrase "and other cosmetically useful additives" from claims 8 and 12. Clarification is requested.

# Claim Rejections - 35 USC § 103

- 5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 6. Claims 1-8, 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Witbeck (US Pat. No. 5,508,027) in further view of Bonfield *et al.* (US Pat. No. 5,728,753).

Witbeck discloses a process and composition for strengthening nails, especially human fingernails. The said composition consists of a hydrophilic polymer, dispersed in an aqueous solution with a fragrance (see Reference claim 3 and column 2, lines 34-37). Witbeck does not

Art Unit: 1615

teach bioactive glass as part of the composition. Bonfield is relied on for the teaching of particulate bioactive glass in a composition that is able to achieve attachment to soft tissue by formation of a layer of hydroxyapatite from said bioactive glass material that increases the presented area and enhances formation of a biological layer (see Reference claim 1 and column 2, lines 37-41). Bonfield also teaches average particle size of bioactive glass ranging from about 0.5 um to about 500 um (see Reference claim 1).

It is the position of the examiner that it would be obvious to one of ordinary skill in this art at the time of the invention to use the teachings of Bonfield with regard to using bioactive glass as a component in a composition to repair nails and soft tissue in the teaching of Witbeck because Bonfield teaches that damaged nails can be strengthened and repaired by adding a composition for an extended period of time as in Witbeck. The addition of Bonfield to Witbeck further enhances the ability of Witbeck's composition to strengthen and treat nails and surrounding tissues. The expected result would be a method for treating nails and adjacent tissues by applying a composition comprising of particles of bioactive glass, an aqueous solvent, a hydrophilic polymer and a fragrance for an extended period of time.

7. Claims 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Witbeck (US Pat. No. 5,508,027) and Bonfield *et al.* (US Pat. No. 5,728,753) in further view of Zook (US Pat. No. 5,181,914).

Witbeck and Bonfield as disclosed above teach a composition for treating nails.

Witbeck and Bonfield do not teach a medicating device for application to nails comprising a viscoelastic gel pad. Zook is relied on for the teaching of a medicating device for human nails

Art Unit: 1615

and adjacent tissues wherein the said gel pad is perfused with one or more pharmacologically active agents (see claims 1 and 9).

It would be obvious to one of ordinary skill in this art, at the time of invention to use the teachings of Zook with regards to perfusing pharmacologically active agents into a medicating device, specifically a viscoelastic gel pad in Wibeck and Bonfield because Zook teaches the use of pharmacologically active agents to help strengthen and treat nails and adjacent tissue as in Wibeck and Bonfield. The expected result would be a medicating device for application to the nails comprising a viscoelastic gel pad perfused with bioactive glass and other pharmacologically active components.

8. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Witbeck (US Pat. No. 5,508,027) and Bonfield *et al.* (US Pat. No. 5,728,753) in further view of Shepherd *et al.* (US Pat. No. 3,914,405).

Witbeck and Bonfield as disclosed above teach a method for treating nails and adjacent tissues. Witbeck and Bonfield do not teach the method for removing such a composition. Shepherd is relied on for the teaching of a method to remove pail compositions by simply washing the hands in water (see column 6, lines 38-45).

It would be obvious to one of ordinary skill in this art, at the time of invention to use the teaching of Shepherd with regard to a method of removing a nail composition by washing with water in the teachings of Witbeck and Bonfield because Shepherd teaches a composition for nails with the expectation of removal from nail after an extended period of time as in Shepherd. The expected result would be a composition for nails and soft tissue with a method of removal by way of simply washing the nails in water.

Art Unit: 1615

9. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Witbeck (US Pat. No. 5,508,027) and Bonfield *et al.* (US Pat. No. 5,728,753) in further view of LeGrow (US Pat. No. 5,403,402).

Witbeck and Bonfield as disclosed above teach a composition for treating nails. Witbeck and Bonfield do not teach the method of applying a protective lacquer coating on the nails following the removal of the composition. LeGrow is relied on for the teaching of removing traces of prior nail lacquer coatings or residues from soap and hand creams, before a new nail lacquer is applied to nails (see column 2, lines 32-35).

It would be obvious to one of ordinary skill in this art, at the time of invention to use the teachings of LeGrow with regards to removing all residues and coatings from the nails before applying a new nail lacquer in Wibeck and Bonfield because LeGrow teaches the application of a composition to nails with the expectation of having the composition contact a clean surface in order to achieve the goal of coating as in Winbeck and Bonfield. The expected result would be the method of applying a protective lacquer coating on the nails following removal of the composition.

#### Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rachel M. Bennett whose telephone number is (703) 308-8779. The examiner can normally be reached on Monday – Friday from 8:00 A.M. to 4:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Art Unit: 1615

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

THURNAN K, RAGE SUPERVISORY PATENT EXAMINER TECHNOLOGY CENTER 1600